

§ 872.6510

subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38799, July 25, 2001]

§ 872.6510 Oral irrigation unit.

(a) *Identification.* An oral irrigation unit is an AC-powered device intended to provide a pressurized stream of water to remove food particles from between the teeth and promote good periodontal (gum) condition.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38800, July 25, 2001]

§ 872.6570 Impression tube.

(a) *Identification.* An impression tube is a device consisting of a hollow copper tube intended to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax, the remaining end is slipped over the tooth to make the impression.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

§ 872.6640 Dental operative unit and accessories.

(a) *Identification.* A dental operative unit and accessories is an AC-powered device that is intended to supply power to and serve as a base for other dental devices, such as a dental handpiece, a dental operating light, an air or water syringe unit, and oral cavity

21 CFR Ch. I (4–1–05 Edition)

evacuator, a suction operative unit, and other dental devices and accessories. The device may be attached to a dental chair.

(b) *Classification.* Class I (general controls). Except for dental operative unit, accessories are exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 65 FR 2315, Jan. 14, 2000]

§ 872.6650 Massaging pick or tip for oral hygiene.

(a) *Identification.* A massaging pick or tip for oral hygiene is a rigid, pointed device intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

§ 872.6660 Porcelain powder for clinical use.

(a) *Identification.* Porcelain powder for clinical use is a device consisting of a mixture of kaolin, feldspar, quartz, or other substances intended for use in the production of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers. The device is used in prosthetic dentistry by heating the powder mixture to a high temperature in an oven to produce a hard prosthesis with a glass-like finish.

(b) *Classification.* Class II.

§ 872.6670 Silicate protector.

(a) *Identification.* A silicate protector is a device made of silicone intended to